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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/661,836	09/12/2003	John Moon	IP-0018-US (830-18US)	8531

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THE SMALL PATENT LAW GROUP LLP
611 OLIVE STREET, SUITE1611
ST. LOUIS, MO 63101

EXAMINER	
HYUN, PAUL SANG HWA	
ART UNIT	PAPER NUMBER
1797	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/661,836	MOON ET AL.	
	Examiner	Art Unit	
	PAUL S. HYUN	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 November 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-53 and 58-60* is/are pending in the application.

4a) Of the above claim(s) *18,33,35,43,44,52 and 53* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17,19-32,34,36-42,45-51,58 and 60* is/are rejected.

7)☒ Claim(s) *59* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/30/07, 1/16/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Remarks

Claims 1-53 and 58-60 are currently pending with claims 18, 33, 35, 36, 39, 43, 44, 52 and 53 being withdrawn in accordance to the restriction requirement dated 1/04/07. In summary, claims 1-17, 19-32, 34, 37, 38, 40-42, 45-51 and 58-60 are pending for examination on the merits. The withdrawn claims are subject to rejoinder upon the allowance of the generic claims.

The amendment to the Specification to update the continuing data filed by Applicants has been acknowledged.

The claim rejections under 35 U.S.C. § 112 cited in the previous Office action has been withdrawn in light of the amendments.

The double patenting rejection will be maintained until a terminal disclaimer is filed.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims **1, 2, 4-8, 19-29, 37, 38, 40-42, 45-48, 50 and 51** are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 4-8, 19-29, 37, 38, 40-42, 45-48, 50 and 51 of copending Application No. 11/063,665, respectively. Although the conflicting claims are not identical, they are not patentably distinct from each other. The claims of the instant application differs from the corresponding claims of 11/063,665 in that the claims of the instant application specify that the code of the microbead extends along the body of the microbead. The claims of the instant application also recite the step of aligning the code relative to a code-reading device. However, it is evident from the claim language that the code of the microbead recited in the claims of 11/063,665 extends along the longitudinal axis of the microbead. It is also evident that the method steps of 11/063,665 naturally accomplish the act of aligning the code of the microbead relative to a code-reading device.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims **1, 2, 4-8, 47, 48 and 50** are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 4-8, 11, 12 and 14 of copending Application No. 11/226,892, respectively. Although the conflicting claims are not identical, they are not patentably distinct from each other. The

claims of the instant application differs from the corresponding claims of 11/226,892 in that the claims of the instant application specify that the code of the microbead extend along the body of the microbead. Moreover, the claims of the instant application further recite the step of aligning the code relative to a code-reading device. However, it is evident from the claim language that the code of the microbead recited in the claims of 11/226,892 extends along the longitudinal axis of the microbead. It is also evident that the method steps of 11/226,892 naturally accomplish the act of aligning the code of the microbead relative to a code-reading device.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim **46** is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Claim 46 recites microbeads comprising both holographic codes and protrusions. The Specification fails to disclose an embodiment that comprises both features. According to the Specification, holographic code is one way of identifying microbeads,

and the protrusions are an alternative way to identify the beads. The Specification does not disclose an embodiment that utilizes both features to identify the beads.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims **47, 50 and 51** are rejected under 35 U.S.C. 102(e) as being anticipated by Empedocles et al. (US 2002/0031783 A1).

Empedocles et al. disclose a positioning device for affixing microbeads thereon (see [0112]).

It should be noted that limitations directed towards the characteristics of the microbeads do not further limit the claimed positioning device because the microbeads are not part of the claimed positioning device..

Claims **47-49** are rejected under 35 U.S.C. 102(e) as being anticipated by Boulton et al. (US 6,027,694)

Boulton et al. disclose a microplate 10 comprising grooves in the form of wells and a shaker for agitating the microplate (see lines 43-53, col. 6).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims **1, 4-7, 16, 26-29 and 58** rejected under 35 U.S.C. 103(a) as being unpatentable over Empedocles et al. in view of Ravkin et al. (US 6,908,737 B2).

Empedocles et al. disclose a system for conducting assays. The system comprises microbeads comprising semiconductor nanocrystals or fluorescent material for identifying the microbeads (see [0094]-[0095]), a light source (e.g. a laser beam) to induce a signal (see [0096]), a holographic transmissive grating, and a detector (e.g. CCD) for sensing the code (see [0018] and [0024]). In one specific embodiment, the system comprises coded beads 64 which bear probes for binding an analyte (see [0112]). The beads may be affixed to a support structure (see [0112]), such as a glass substrate (see [0151]) to enable the beads to be accurately aligned with imaging optics 58 and sensor system 66 (see [0113]). The system and the method disclosed by Empedocles et al. differ from the claimed invention in that Empedocles et al. do not disclose that the beads have an elongated shape. In addition, the reference does not disclose that each bead is coded along its longitudinal axis.

With respect to the shape of the beads, the use of cylindrical microbeads for conducting assays is well known in the art. Ravkin et al. disclose a system for conducting assays. The system utilizes coded microbeads (see lines 29-30, col. 9) wherein the microbeads are cylindrically shaped (see lines 9-10, col. 9) and has dimensions ranging between 1-200 microns (see line 53, col. 4). In light of the disclosure of Empedocles et al. stressing the importance of the alignment between the microbeads and the optical system, it would have been obvious to one of ordinary skill in the art to incorporate cylindrically shaped microbeads as disclosed by Ravkin et al. to the system disclosed by Empedocles et al. since cylindrically shaped beads are easier to orient and align than spherical beads.

With respect to the location of the holographic code relative to the microbeads, Empedocles et al. disclose the importance of the alignment between the beads and the imaging optics/sensor (see [0114]). Specifically, the reference discloses that in order to obtain an accurate spectra, the beads must be aligned along an optical axis. In light of the disclosure, it would have been obvious to one of ordinary skill in the art to encode each and every bead along its longitudinal axis to preserve the consistency in encoding the beads, which would facilitate alignment of the beads with the optical axis. Similarly, with respect to claim 7, although Empedocles et al. do not explicitly disclose immobilizing the beads along its pitch and yaw axes, it would have been obvious to one of ordinary skill in the art to align the beads along its pitch and yaw axes to facilitate the alignment of the beads relative to the optical axis.

Claims **2, 3, 8-15, 17, 30, 34, 42 and 45** are rejected under 35 U.S.C. 103(a) as being unpatentable over Empedocles et al. in view of Ravkin et al. as applied to claims 1, 4-7, 16, 26-29 and 58 above, and further in view of Pope (US 2002/0197456 A1).

Empedocles et al. disclose several ways to immobilize microbeads onto a substrate, including wells that are specifically dimensioned to accommodate a single microbead therein and further comprising suction holes (see [0150]-[0157]). However, neither Empedocles et al. nor Ravkin et al. disclose a substrate comprising elongated grooves.

Pope discloses a biochip comprising flat-bottomed and V-shaped troughs for supporting microspheres (see Figs. 10 and 17). In light of the disclosure of Pope, it would have been obvious to one of ordinary skill in the art to provide the substrate structure disclosed by Empedocles et al. with V-shaped or flat-bottomed troughs for supporting the modified microbeads. The troughs would be more suitable than wells for supporting cylindrically shaped microbeads.

With respect to claims 3, 17 and 42, although the references do not disclose the step of shaking the substrate to encourage placement of the microbeads into their respective positions, it would have been obvious to one of ordinary skill in the art to do so manually or by using a device to save time in aligning the microbeads.

With respect to claim 12, the references do not explicitly disclose the spacing of the grooves. Nonetheless, it would have been obvious to one of ordinary skill in the art to optimize the capacity of the substrate by adjusting the spacing of the grooves such that it is between 1-2 times the diameter of the microbeads.

With respect to claim 30, the claim does not further limit the claimed method because it does not appear that photolithographic process produces features on a plate that is structurally different from features formed by any other method, specifically micromachining as disclosed by Empedocles et al.

Claims **19-25, 31, 32 and 37** are rejected under 35 U.S.C. 103(a) as being unpatentable over Empedocles et al. in view of Ravkin et al. as applied to claims 1, 4-7, 16, 26-29 and 58 above, and further in view of Seul et al. (US 2003/0082587 A1).

Neither Empedocles et al. nor Ravkin et al. disclose the claimed plate.

Seul et al. disclose a substrate configured to support microbeads. The substrate can be made from a material, such as glass, that has low-fluorescence and high reflectivity (see [0051]). Alternatively, the substrate can be coated with material having the desired characteristics. The substrate can further comprise features formed by means of photoresist (see [0068]) as well as a cover to immobilize the microbeads (see [0095]).

With respect to claims 19-24, in light of the disclosure of Seul et al., it would have been obvious to one of ordinary skill in the art to provide the substrate of the modified Empedocles et al. device with a cover that can protect the microbeads.

With respect to claims 25 and 31, in light of the disclosure of Seul et al., it would have been obvious to one of ordinary skill in the art to manufacture the substrate disclosed by Empedocles et al. using a photoresist. That said, since SU-8 is a well

known negative photoresist, it would have been obvious to one of ordinary skill in the art to use SU-8 to form the features of the modified Empedocles et al. chip.

With respect to claims 32 and 37, in light of the disclosure of Seul et al., it would have been obvious to one of ordinary skill in the art to manufacture the substrate disclosed by Empedocles et al. from low fluorescence glass to minimize interference during measurements. Likewise, it would have been obvious to provide a mirror coating to the substrate disclosed by Empedocles et al. to optimize the reflectivity of the substrate.

Claims **38, 40 and 41** are rejected under 35 U.S.C. 103(a) as being unpatentable over Empedocles et al. in view of Ravkin et al. as applied to claims 1, 4-7, 16, 26-29 and 58 above, and further in view of Phan et al. (US 2003/0082568 A1).

Empedocles et al. disclose a step of centrifuging the microbeads (see [0090]). However, neither Empedocles et al. nor Ravkin et al. disclose a disk comprising radial grooves.

Phan et al. disclose a system for conducting immunoassays. The system comprises a disk comprising radial channels on which microbeads are disposed. The radial channels enable the microbeads to be centrifuged (see [0197]). In light of the disclosure of Phan et al., it would have been obvious to one of ordinary skill in the art to provide the modified Empedocles et al. apparatus with a disk-shaped substrate with radial channels so that the microbeads can be centrifuged.

Claim **60** is rejected under 35 U.S.C. 103(a) as being unpatentable over Empedocles et al. in view of Ravkin et al. as applied to claims 1, 4-7, 16, 26-29 and 58 above, and further in view of Barlow et al. (US 5,682,244).

Neither Empedocles et al. nor Ravkin et al. disclose a numeric, holographic code comprising a series of bits.

Barlow et al. disclose microspheres coded with a binary code (see lines 40-55, col. 9). The reference discloses that a binary code enables complex coding. In light of the disclosure of Barlow et al., it would have been obvious to one of ordinary skill in the art to code the modified Empedocles et al. beads using binary codes if complex coding is required.

Allowable Subject Matter

Claim 59 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter:

Empedocles et al. disclose microbeads comprising a code that can be transformed into a holographic signal by filtering the code through a wavelength dispersive element. However, Empedocles et al. do not disclose a microbead comprising a holographic code wherein the code is defined by refractive index variations extending along the longitudinal axis of the microbead.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new grounds of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL S. HYUN whose telephone number is (571)272-8559. The examiner can normally be reached on Monday-Friday 8AM-4:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Paul S Hyun/
Examiner, Art Unit 1797

/Jill A. Warden/
Supervisory Patent Examiner, Art Unit 1797